

About ClinicalTrials.gov

- Clinical Trials = research studies in which new treatments are tested in patients to see if they are safe and effective.
- Provides easy access to information on clinical trials for a wide range of serious or lifethreatening diseases and conditions.
- Language used in the text is intended to be suitable for the general public.
- Developed by the U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), in collaboration with NIH Institutes and the Food and Drug Administration (FDA).
- Contains over 5,000 clinical studies sponsored primarily by NIH. Trials from other Federal agencies and the pharmaceutical industry will be included later.
- Available at clinicaltrials.gov
- Alternatively click on the *ClinicalTrials.gov* image on NLM's home page.





Menu bar

- Appears directly below the logo on all pages.
- Facilitates navigation.
- Click on **Home** to return to the home page of *ClinicalTrials.gov*.
- **Search** returns to a cleared out search query box.
- Use **Browse** to reach the Browse option page (discussed later in this workbook).
- Use **Resources** to learn more about clinical trials. This page also provides links to other consumer health-oriented resources.
- Click on **Help** to get detailed search information.
- Click on **What's New** to see a variety of information: the FDA guidance document, Frequently Asked Questions, linking information, and other timely information.
- Click on **About** to read an overview of *ClinicalTrials.gov*.

The Footnote

U.S. National Library of Medicine, Contact NLM Customer Service
National Institutes of Health, Department of Health & Human Services
Copyright and Privacy Policy, Freedom of Information Act, Accessibility

- Click on **National Library of Medicine** to reach NLM's home page.
- Click Contact NLM Customer Service to send a customer service inquiry.
- Click **National Institutes of Health** (NIH) to reach NIH's home page.
- Click **Department of Health & Human Services** (DHHS) to reach its home page.
- Click **Freedom of Information Act (FOIA)** to reach the NIH FOIA Office home page.
- Click on **Copyright and Privacy Policy** to NLM's copyright and privacy policy page.

Finding Clinical Trials in ClinicalTrials.gov

There are three ways to look for clinical trial records:

- Use **Basic Search** to find information broadly.
- Use **Focused Search** to find studies meeting specific criteria.
- Use **Browse** to find studies sorted by condition or by sponsor.



Basic Search screen:

• Type your search term(s) in to the query box.



The U.S. National Institutes of Health, through its National Library of Medicine, has developed ClinicalTrials.gov to provide patients, family members and members of the public current information about clinical research studies. Before searching, you may want to learn more about clinical trials and more about this Web site. Check often for regular updates to ClinicalTrials.gov.

Search Clinical Trials

Enter words or phrases, separated by commas:

macular degeneration Search Tips

Search by Specific Information

Focused Search - search by disease, location, treatment, sponsor...

Browse

<u>Browse by Condition</u> - studies listed by disease or condition <u>Browse by Sponsor</u> - studies listed by funding organization

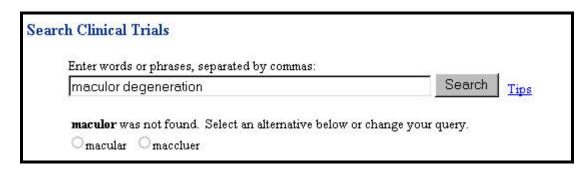
Resource Information

<u>Understanding Clinical Trials</u> - information explaining and describing clinical trials <u>MEDLINE plus</u> - authoritative consumer health information <u>NIH Health Information</u> - research supported by the National Institutes of Health healthfinder® - consumer health and human services information

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Spell Check

• Some misspelled words can be recognized, and suggestions provided:

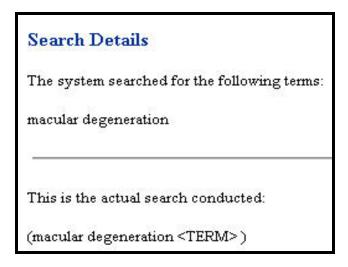


Working with Results

• You can see how your search was handled by clicking on the button on the Search results screen.



You are then taken to the Search Details screen:



Results (cont'd)

- The results of your search will be displayed in a brief list format in a ranked order based on your search criteria.
- The current status of the trial (e.g., recruiting), title, and conditions being studied (e.g., rheumatoid arthritis; diabetes; breast cancer) are shown for each clinical trial.
- The display default is for "recruiting" and "not yet recruiting" trials. To see *all* trials (including trials no longer recruiting), click on the box next to "Show all trials..."
- If you want to see the details of a trial use the title link.
- If you want to see the details of multiple trials, you can select the ones you like (checkbox) and then use the Display Selected Studies button.

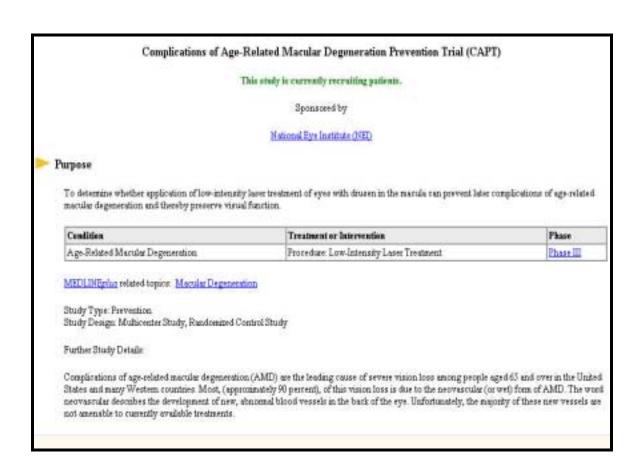


Trial Details

The trial details include:

- · Brief Title
- Name of Sponsoring institute
- Purpose
- Name of Disease or Condition
- Name of the Treatment or Intervention
- Phase
- Links to MEDLINE*plus* topics
- Study Type and Design

- · Official Title
- Detailed Description
- Eligibility information
- Dates of the study
- Location and Contact Information
- More Information supplied by sponsoring organization
- References



Record continues on the next page.

The CAPT is a multi-center, prospective, randomized clinical trial designed to assess the safety and effectiveness of low-intensity laser treatment in preventing vision loss among patients with large drusen in both eyes. Eligible patients will have one eye randomly assigned to laser treatment performed by a CAPT-certified ophthalmologist. The other eye is not treated. Both eyes are observed carefully for any changes for a period of five years. The effectiveness of the treatment will be assessed using the following criteria:

Change in visual acuity (primary outcome measure of the study)

Incidence of complications of AMD such as neovascularization, serous detachment of the pigment epithelium, and geographic atrophy

Changes in contrast threshold and critical print size for reading

Quality of life assessments for patients, using the Visual Function Questionnaire 25 (VFQ-25), will be conducted at the time of enrollment and at 5 years.

Eligibility

Ages Eligible for Study: 50 Years and above, Genders Eligible for Study: Both

Criteria

Patients eligible for CAPT can be either male or female and meet the following criteria: Age at least 50 years old

Vision in each eye must measure 20/40 or better.

At least 10 large drusen in each eye

Available for follow-up examinations for 5 years after enrollment

Final eligibility is determined through a detailed eye examination by a CAPT-certified ophthalmologist.

Location and Contact Information

Maureen G. Maguire, Ph.D., Director 3535 Market Street, Suite 700 Philadelphia, Pennsylvania, 19104-3309, United States 1-215-615-1500

Arizona

Retinal Consultants of Arizona, Ltd., 560 West Brown Road, Suite 2004 Mesa, Arizona, 85201, United States; No longer recruiting

Donald W. Park, M.D. 1-602-402-0409

Arizona

Retinal Consultants of Arizona, Ltd., 10615 West Thunderbird Boulevard Suite D-500 Sun City, Arizona, 85351, United States; No longer recruiting

Donald W. Park, M.D. 1-602-402-0409

California

Schatz, McDonald, Johnson, Ai, One Daniel Burnham Court, Suite 210C San Francisco, California, 94109, United States; No longer recruiting

Robert M. Johnson, M.D. 1-415-441-0906

This is a partial screen capture of the Location and Contact Information.

Detailed Display (cont'd)



Study ID Numbers NEI-70 NLM Identifier NCT00000167 Date study started May 1, 1999 Record last reviewed October 23, 1999 Last Updated October 23, 1999

Focused Search

- On the Home or Search screen, use the link: **Focused Search**
- This option lets you conduct a more structured search.
- It is not necessary to fill in all the boxes.
- The labels to the left of each box are links to further explanation.

Focused Search	
Use this form to focus your search. Fill in any or all of the boxes below. Click on the label to the left of each box for further explanation.	
	Search Tips
Disease or Condition:	asthma
Experimental Treatment:	
Trial Location:	colorado
Additional Terms:	
Age Group:	☐ Child (birth-17) ☐ Adult (18-65) ☐ Senior (66+)
Study Phase:	□ Phase I □ Phase II □ Phase IV
Supported By:	□ NIH □ Other Federal Agency □ Industry □ University/Organization
Study ID Number:	
	✓ Include synonyms in search
	Search
	Basic Search

Browse

Browsing allows you to look through the entire list of trials by two categories:

- Condition
- Sponsor

Browse Clinical Trials

Show all trials, including those no longer recruiting patients.

Browse by Condition

Alphabetically

By Disease Heading

Browse by Sponsor

National Institutes of Health

Other Federal Agency

Industry

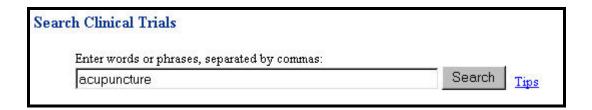
University/Organization

Practice Exercises

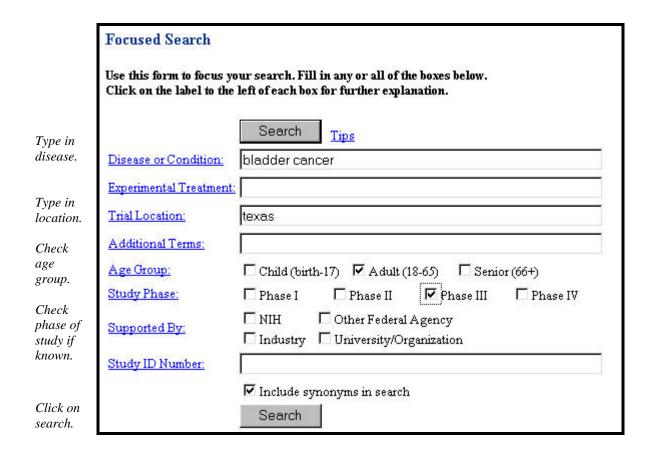
- 1. Are there any trials studying acupuncture?
- 2. Find Phase III clinical trials for bladder cancer for an adult patient living in Texas. (Hint: Use Focused Search).
- 3. Using the Browse by Condition mode, retrieve the clinical trials studying Abdominal Neoplasms.

Suggested Answers

1. Are there any trials studying acupuncture?



2. Find Phase III clinical trials for bladder cancer for an adult patient living in Texas. (Hint: Use Focused Search).



3. Using the Browse by Condition mode, retrieve the clinical trials studying Abdominal Neoplasms.

You can select the Browse mode from the Home page:

Browse

Browse by Condition - studies listed by disease or condition Browse by Sponsor - studies listed by funding organization

OR

You can click on Browse from the Menu Bar:



You can then choose either route offered: Alphabetically or by Disease Heading:

Browse : By Condition

Show all trials, including those no longer recruiting patients.

- 1. Alphabetically
- 2. By Disease Heading

<u>NOTES</u>